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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,683	07/01/2003	Burke Barrett	001301-00349	3429

27557 7590 04/05/2006

BLANK ROME LLP
600 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,683	BARRETT ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the species in claim 38 involving stimulating the patient's stomach must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation of claim 38 involving indirect application of stimulation to the right and left vagi by stimulating the stomach or other visceral organ is not found.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 3-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,587,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 is merely a broader version of claim 1 in the '719 patent (the patented claim includes the additional wording "and intermittently" not found in the application claim). Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1 and 3-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Pat. No. 5,514,175) in view of Zabara (Pat. No. 5,540,734).

Regarding claim 1 and claims of similar scope, bilateral stimulation of the patient's tenth cranial nerve (vagus) is accomplished via stimulus generator 11 and 11' as discussed in col. 6, lines 40-56 in order to control maladies such as obesity (note the sentence abridging columns 6 and 7, as well as the discussion of patient F in cols. 7 and 8). Although Kim et al. do not *directly* stimulate the right and left vagus nerves (Merriam Webster's defines the word *directly* to connote "...in immediate physical contact"), a person of ordinary skill in the art given the disclosure of Kim et al. would have seen the obviousness of directly applying the stimulus to the nerves to effect obesity control because it is of general knowledge in the art that nerves may effectively be stimulated either indirectly through the skin with an external stimulator unit, or directly through the use of an implanted electrode and/or stimulator (i.e., a stimulated nerve is a stimulated nerve regardless of where the stimulation originated). In support, Zabara discloses that prior artisans have recognized that nerves such as the vagus can be stimulated either via implantable or external neurostimulating devices (see col. 1, lines 27-32). The motivation for such an implanted arrangement would be to make the system unobtrusive and aesthetically pleasing to the user --especially a user that might be embarrassed to wear an external treatment device in public. Furthermore, an external system must rely on the individual to remember to use it and properly position it if treatment is to be effective. An implantable unit eliminates the conscious effort a patient must exercise in order to benefit from the treatment. Finally, it is of general knowledge in the art that implantable systems may be necessary when precise stimulation of the nerve is required so as to avoid unintended stimulation. Because an implanted electrode can be located in immediate contact with the target nerve, inadvertent stimulation that may have resulted from extraneous sources can be avoided.

Regarding claim 3 and related claims, it is of general knowledge in the medical art that therapuetical times are highly dependent upon the condition of the patient under

treatment, with the range of treatment times established by clinical studies and routine experimentation as often required by the FDA. The term "chronic" is also a relative term that has not been defined by the applicants with exactness or specificity. The applicants further state that chronic stimulation is preferred over acute stimulation, but not required (page 9, lines 1-7). Those of ordinary skill in the medical arts would have therefore considered the matter of treatment time to be an obvious matter of design dependent upon the particular individual under treatment.

Regarding claim 5 and related claims, while Kim et al. do not discuss the particular timing of treatment in relation to the circadian cycle, it would have been obvious to anyone of ordinary skill in the art looking to control obesity, to initiate treatment during those periods of the day when the patient is feeling most hungry and would therefore be most likely to eat (i.e., during mealtimes).

Regarding claim 6 and related claims, note external ON button 10. The examiner takes Official Notice that it is old and well known to provide a measure of patient control to fully implanted or partially implanted devices as well.

Concerning claim 9 and related claims, Kim et al. disclose in col. 6, lines 40-56 that all the elements thus described may not be present in, on, or over both ears, further stating that one pulse generator may be used. This of course naturally implies that it would have been obvious to incorporate separate nerve stimulator generators. The choice to use one or two generators would have clearly been considered a matter of obvious design by those of ordinary skill in the art, with trade-offs between uniform manufacturing techniques and unit cost playing a role in the decision.

Concerning claims 12 and 18, the examiner considers any position above the diaphragm to be supra diaphragmatic.

In reference to claim 13, since the pulse current of Kim et al. is less than 6 mA, the examiner considers it to be inherently below a retching level.

Regarding the on-off duty cycle of claim 14, note col. 5, lines 38-45. The employment of such interim periods is clearly an application dependent parameter based upon treatment optimization. Given that Kim et al. refer to the use of on-off periods, those of ordinary skill in the art desiring to maximize obesity treatment

effectiveness, would have seen the obviousness of utilizing such a pulse parameter to provide the most efficient and effective treatment possible.

Concerning claims 15 and 19, by definition it appears to be inherent that pulses would be applied during the on period of any duty cycle and not during the off period.

Concerning recitations of pulse width and duty cycle ratio in claims 21, 23, 28 and 30, while Kim et al. do not elaborate on such specifics, the exact pulse parameters chosen to produce the sensation of saiety from patient-to-patient would have been considered a matter of obvious design by artisans of ordinary skill in the art. Routine experimentation and optimization of parameters has been considered by the courts to be a matter of obvious design, lacking any unexpected results from the ranges recited. Attention is invited to page 4, lines 10-12 of the present specification.

Regarding claim 38, Kim et al. do not disclose application of the electrical signal to the right and left vagi indirectly by stimulating the stomach or other visceral organ. The applicants have not disclosed that the stimulation of vagi from other points in the body provides any particular advantage or solves any particular problem with the treatment of obesity over that provided by supra diaphragmatic stimulation. One would further expect the invention to work equally well no matter where the origin of vagi stimulation. The stomach, for example, is innervated by the vagi. It would be logical therefore to conclude that stimulation of the vagi at the stomach would also create the same feelings of satiety desired with the Kim et al. invention. The exact location chosen would clearly rest with the prerogative of the surgeon and would ultimately depend upon the condition of the patient under treatment.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 3, 2006

KENNEDY SCHAETZLE
PRIMARY EXAMINER